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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,538	10/02/2003	Thomas C. Kienzle III	132372 (14089US02)	9546

23446 7590 12/28/2010
MCANDREWS HELD & MALLOY, LTD
500 WEST MADISON STREET
SUITE 3400
CHICAGO, IL 60661

EXAMINER	
SEVILLA, CHRISTIAN ANTHONY	

ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
12/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/677,538	**Applicant(s)** KIENZLE ET AL.
	Examiner CHRISTIAN SEVILLA	**Art Unit** 3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2010*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 15-24* is/are pending in the application.
  4a) Of the above claim(s) *23 and 24* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1,3-13 and 15-22* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Amendment filed October 19, 2010 is acknowledged. Amended claims 1, 13, and 23 have been entered. Claims 1, 3-13, and 15-24 are pending.

Response to Arguments

Applicant's arguments with respect to claims 1 and 13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-8, 12, 13, 15, 18, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle (US 6478802; “Kienzle” herein) in view Williams (US 6190395) and further in view of Erdman, *et al.* (US 6022150).

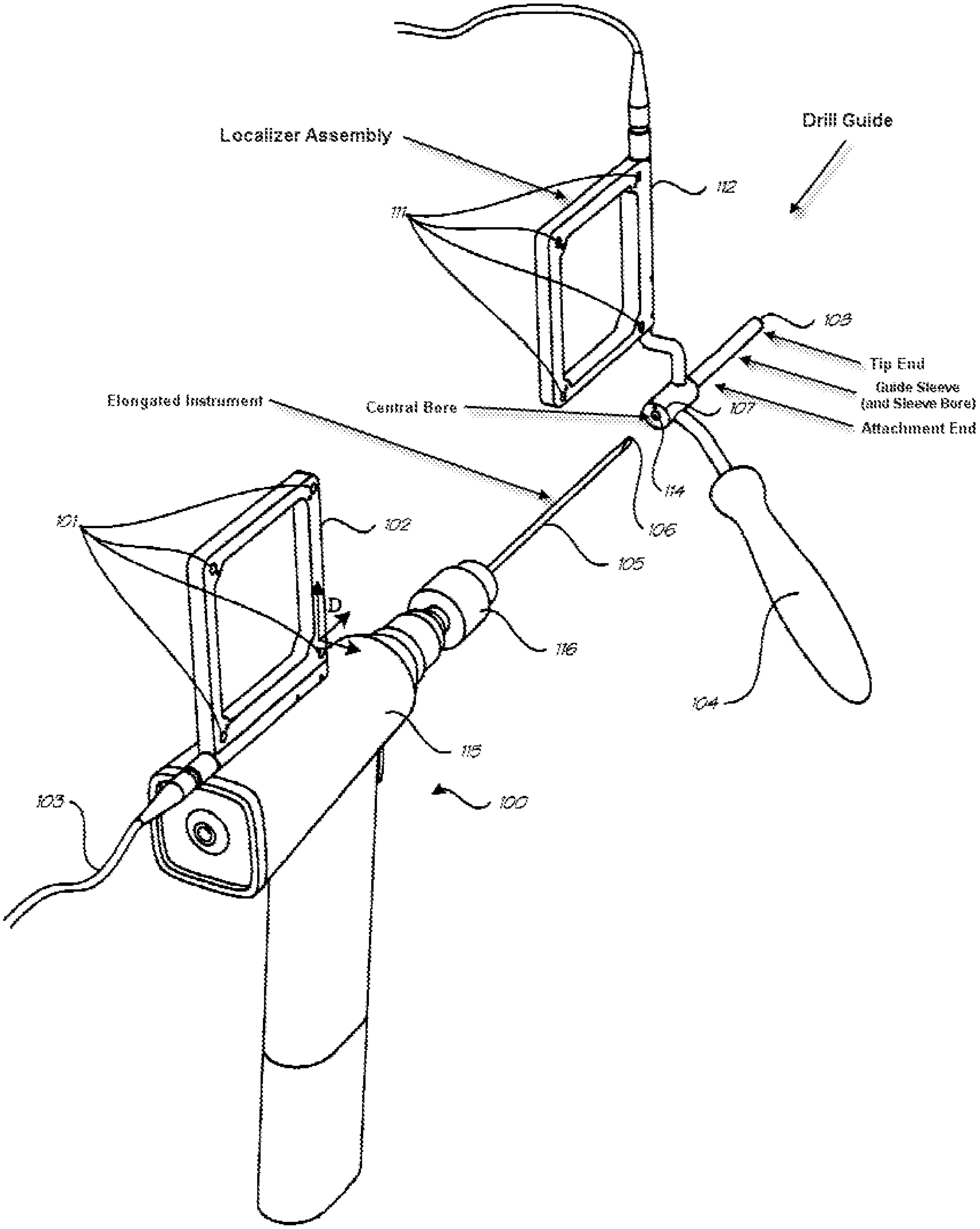

Localizer Assembly
Drill Guide
Tip End
Guide Sleeve
(and Sleeve Bore)
Attachment End
Central Bore
Elongated Instrument
D

Fig. 1

Regarding claim 1, 6, 13, and 18, Kienzle discloses an instrument guide for use with an elongated instrument (105) or drill bit (105) and a computer assisted surgery tracking system including a localizer assembly (112) having a central bore (114); a handle assembly (104) connected to the localizer assembly (112); a guide sleeve wherein the guide sleeve has a tip end, an attachment end, and a sleeve bore, *as shown in annotated Fig. 1 above*; the sleeve bore has a fixed position relative to the localizer assembly (112); the localizer assembly (112) is used to determine the trajectory of the sleeve bore; a computer that displays an image of the surgical site; and a second collar (e.g. structure around bore 114).

Kienzle fails to disclose the localizer assembly is connected to a first collar; the first and second collars being connected to each other by a locking mechanism and engaging each other such that the first and second collars rotatably move relative to each other in an unlocked position.

Williams discloses a localization device (34) removably attached to a surgical tool (32) by means of a clamping band (46; Fig. 2). The construction of the clamping band (46) is such that its size can accommodate any instrument diameter {col. 5, lines 33-37}. In use, the mounting assembly may be mounted to a plurality of surgical instruments to be used in a surgical procedure and can be quickly coupled to any surgical instrument {col. 7, line 65 – col. 8, line 4}. A clamp nut (52) can be tightened to draw loop portion (71) of the clamping band (46) snugly about surgical tool or instrument (32) {col. 6, lines 37-39}.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Kienzle in view of Williams to include the localizer assembly is connected to a first collar; the first and second collars being connected to each other by a locking mechanism and engaging each other such that the first and second collars rotatably move relative to each other in an unlocked position. Doing so would have permitted mounting the localizer to a plurality of surgical instruments, thereby facilitating use of the localizer with a wider range of surgical instruments.

Kienzle further fails to disclose the attachment end is configured to be inserted into the central bore such that a portion of the attachment end is received inside the central bore and engages the central bore such that the attachment end is rigidly connected to the central bore; the attachment end being configured to be disconnected from the central bore by removing the portion of the attachment end that is received inside the central bore from the central bore; and the at least one guide sleeve includes a groove and a pin, wherein when the at least one guide sleeve is inserted into the central bore, the groove receiving a ring in the central bore and the pin being received in a hole in the central bore to rigidly maintain the at least one guide sleeve within the central bore.

Erdman discloses a connector assembly comprising a ferrule assembly 1 within a conventional bayonet style coupling nut 4, the assembly retained by C-ring 7 held in groove 8 (col. 2, line 67 – col. 3, line 3; Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified Kienzle in view of Erdman to include the attachment end is configured to be inserted into the central bore such that a portion of the attachment end is received inside the central bore and engages the central bore such that the attachment end is rigidly connected to the central bore; the attachment end being configured to be disconnected from the central bore by removing the portion of the attachment end that is received inside the central bore from the central bore; and the at least one guide sleeve includes a groove and a pin, wherein when the at least one guide sleeve is inserted into the central bore, the groove receiving a ring in the central bore and the pin being received in a hole in the central bore to rigidly maintain the at least one guide sleeve within the central bore. Doing so would have attached the guide sleeve in a more separable manner so that the guide sleeve can be more easily replaced with other guide sleeves.

Regarding claim 7, Kienzle further discloses an elongated instrument, in which the elongated instrument is a drill bit (105).

Regarding claim 12, the guide sleeve also includes a feature (constituted by the tubing portion connecting element 112 to element 108). The feature, as shown in Figure 1, is in a fixed (and thus known) relationship with the localizer assembly, such that the localizer assembly (112) is used to determine the position of the feature.

Regarding claim 15, the attachments are fixed at a position/location relative to the localizing assembly (112).

Regarding claim 22, Kienzle further discloses a computer that calculates the position of the attachment, and displays a graphic representation of the attachment (Fig. 4).

Claims 8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle in view Williams and Hearn, as above, and further in view of Greenberg, *et al.* (US 5743916; “Greenberg” herein).

Kienzle fails to disclose a plurality of guide sleeves having varying inner diameters as claimed.

Greenberg discloses a drill guide including a plurality of guide sleeves of varying diameter (Fig. 4A, element 165; also col. 6, lines 35-51), each capable of being slidably removably connected to a central bore mounted on a handle.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified Kienzle in view of Williams and Hearn, as above, and further in view of Greenberg to include a plurality of guide sleeves having varying inner diameters, in order to accommodate drill bits of different diameters.

Claims 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle in view Williams and Hearn, as above, and further in view of Gisin, *et al.* (US 5507801; “Gisin" herein)

Kienzle fails to disclose the at least one guide sleeve comprises a plurality of guide sleeves of varying lengths.

Gisin discloses a drill guide in which an internal cylinder is slidingly positioned in an outer cylinder {col. 1, lines 45-48}; and the internal cylinder may be built in various lengths {col. 2, lines 9-10}.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Kienzle in view of Williams and Hearn, as above, and further in view of Gisin to construct the guide sleeve comprising a plurality of guide sleeves having varying lengths. Doing so would have permitted the drilling of holes to more precise desired depths, thereby avoiding injury due to overdrilling.

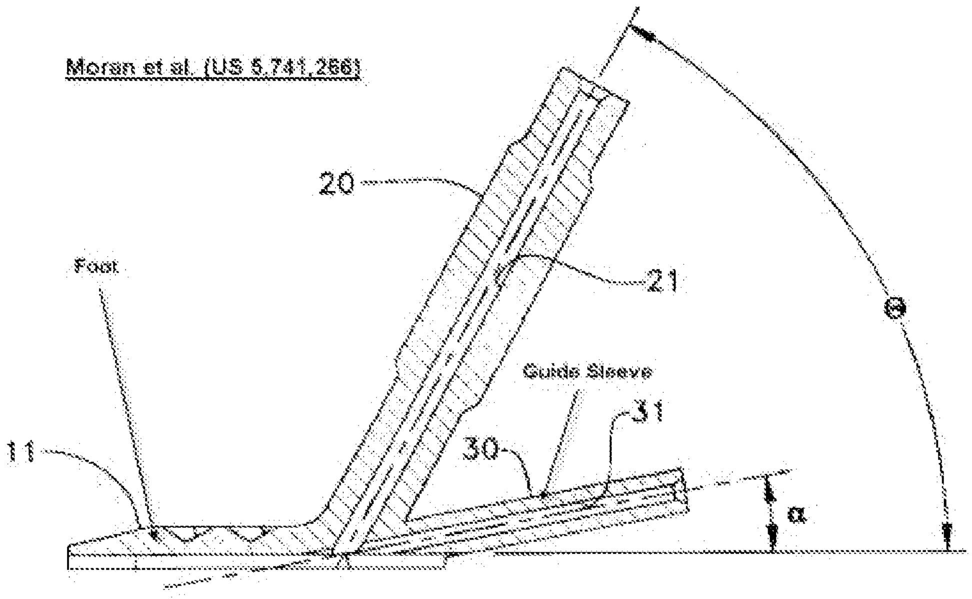
Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle in view of Williams and Hearn, as above, and further in view of Mattson, *et al.* (US 3341235; “Mattson” herein).

Kienzle fails to disclose each of the handle assembly and the localizer assembly is configured to rotate about the central bore such that the handle assembly and the localizer assembly are movable relative to each other.

Mattson discloses a device wherein an auxiliary handle (57) adjustable about and along a main guide handle (38) {col. 1, line 64-66}.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Kienzle in view of Williams and Hearn, as above, and further in view of Mattson to construct each of the handle assembly and the localizer assembly configured to rotate about the central bore such that the handle assembly and the localizer assembly are movable relative to each other. Doing so would increased the adjustability of the handle relative to the localizer to better accommodate the geometry of the surroundings in which the device is used.

Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle in view of Williams and Hearn, as above, and further in view of Moran et al. (US 5,741,266).



Kienzle fails to disclose a foot oriented at a desired angle. Attention, however, is directed to the Moran et al. reference (see marked up figure above), which discloses another medical device having a guide sleeve (30), wherein the guide sleeve has a foot (11) oriented at a desired angle (α) to allow the guide sleeve to contact the treatment location at the preferred angle. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the Kienzle reference by employing a guide sleeve having a foot at a desired angle, in view of Moran et al., in order to orient the guide sleeve (21) at the desired angle (α) to allow the guide sleeve to contact the treatment location at the preferred angle.

Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle in view of Williams and Hearn, as above, and further in view of Karas et al. (US 4,788,970).

Kienzle fails to disclose the tip end having serrations. The Karas et al. reference discloses another medical device having a drill setting guide for drilling holes in bone that include drill guide bushes (2) having the ends provided with blades or serrations (5) for engaging a treatment portion of the user or patient (col. 5, lines 15-22). Therefore, it would have been obvious to a person having ordinary skill in the art to have modified the Kienzle reference to include tip end having blades or serrations, in view of the Karas et al., to allow the device to more securely engage a treatment portion of the patient.

Claims 5, 9, and 20 are rejected under U.S.C. 103(a) as being unpatentable over Kienzle in view of Williams and Hearn, as above, and further in view of Sati, *et al.* (US 2002/0055679; “Sati” herein).

Kienzle discloses the localizer assembly comprises eight emitters (111) (col. 3, lines 44-45). The emitters may comprise visible spectrum emitters (col. 3, line 50). The emitters are viewable by an optical localizer (col. 3, line 24)

Kienzle fails to disclose the localizer assembly includes an electromagnetic receiver.

Sati discloses a medical device in which objects to be tracked include markers which can be configured to emit, receive, or reflect energy, such as light {para. [0010], lines 6-8}. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Kienzle in view of Sati to construct the localizer assembly includes electromagnetic receivers since doing so would have been a mere reversal of the essential working parts of the device, involving only routine skill in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN SEVILLA whose telephone number is (571)270-5621. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THOMAS C. BARRETT can be reached on (571) 270-1935. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTIAN SEVILLA/
Examiner, Art Unit 3775
/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733